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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,248	09/17/2001	Leo Martis	DI-4641 CONT	8992

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EXAMINER	
KEYS, ROSALYND ANN	
ART UNIT	**PAPER NUMBER**
1621	9

DATE MAILED: 07/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/955,248	MARTIS ET AL.	
	Examiner	Art Unit	
	Rosalynd Keys	1621	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 May 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of Claims

1. Claims 1-16 are pending.

Claims 1-16 are rejected.

Information Disclosure Statement

2. The information disclosure statement filed My 7, 2002 has been considered except for the references, which are lined through. The lined through references were not considered because they fail to comply with 37 CFR 1.98(a)(3) because the IDS does not include a concise explanation of their relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information. A concise explanation of their relevance is required because each of the patents lined through is not in the English language.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, and 4-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Schambye et al. (Peritoneal Dialysis International, Vol. 13, Supplemental 2, October 1992, pp. S116-S118) in view of Zander (US Patent No. 5,296,242).

Schambye et al. disclose continuous ambulatory peritoneal dialysis (CAPD) solutions having bicarbonate concentrations ranging from 10-27 mM, lactate concentrations ranging from 20.0-6.7 mM (see abstract on page S116). The most advantageous CAPD solution has a bicarbonate concentration of approximately 20 mM, a lactate concentration of 12.5 mM, and a pH of approximately 7.2 (see page S116, abstract and page S118). Since, Schambye et al. disclose a CAPD solution which has the claimed bicarbonate and weak acid concentrations then the CAPD solution of Schambye et al. inherently exhibit the claimed CO_2 partial pressure (see In re King, 801 F.2d 1324, 231 USPQ 136 (Fed. Cir. 1986), since it is the bicarbonate and weak acid that determine the CO_2 partial pressure (see Zander at column 3, lines 11-16, wherein it is taught that the reaction between the bicarbonate and metabolizable organic acid produces the CO_2 partial pressure).

The burden shifts to the Applicants to prove that the CAPD solution of Schambye et al. do not necessarily or inherently possess the characteristics of their claimed peritoneal dialysis solution (see In re Fitzgerald, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) and In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977).

5. Claims 1, 2, and 4-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Veech (US 4,663,166) in view of Zander (US Patent No. 5,296,242).

Veech discloses preferred peritoneal dialysis solutions comprising osmotically active substances such as glucose (dextrose, 83-237 mmole/L), sodium (130 to 145 mmole/L), chloride (93 to 102 mmole/L), calcium (1 to 1.5 mmole/L), magnesium (0.3 to

1 mmole/L), bicarbonate (25 to 30 mmole/L), lactate$^-$/plus pyruvate$^-$ (2 to 12) and carbon dioxide (0 to 2 mmole/L), see column 41, table VIII and column 37, line 41.

Since, Veech discloses a peritoneal dialysis solution which has the claimed bicarbonate and weak acid concentrations then the peritoneal dialysis solution of Veech inherently exhibits the claimed CO_2 partial pressure (see In re King, 801 F.2d 1324, 231 USPQ 136 (Fed. Cir. 1986), since it is the bicarbonate and weak acid that determine the CO_2 partial pressure (see Zander at column 3, lines 11-16, wherein it is taught that the reaction between the bicarbonate and metabolizable organic acid produces the CO_2 partial pressure).

The burden shifts to the Applicants to prove that the peritoneal dialysis solution of Veech does not necessarily or inherently possess the characteristics of their claimed peritoneal dialysis solution (see In re Fitzgerald, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) and In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schambye et al. (Peritoneal Dialysis International, Vol. 13, Supplemental 2, October 1992, pp. S116-S118) in view of Zander (US Patent No. 5,296,242).

Schambye et al. disclose a peritoneal dialysis solution as described above. Schambye et al differ from the instant invention in that Schambye et al. do not specifically teach that the carbon dioxide partial pressure is approximately the same as the carbon dioxide partial pressure of blood.

Zander discloses sterilizable aqueous solutions that contain the claimed concentrations of the bicarbonate and weak acid, as well as the claimed carbon dioxide partial pressure (see column 2, line 35 to column 6, line 27). Zander discloses that preliminary research revealed that dialysis solutions are particularly suitable if their pH-value, bicarbonate concentration and CO_2 partial pressure correspond to the physiological blood plasma values (see column 2, lines 35-39). These physiological values are for pH value 7.40+\-0.05, for the bicarbonate concentration 24 mmole/l and for the CO_2 partial pressure 40 mm Hg (see column 2, lines 40-43). Zander discloses that using pH-values (7.40+\-0.05), bicarbonate concentrations (24 mmole/L) and CO_2 partial pressures (40 mm Hg) that correspond to physiological blood plasma values would prevent alkalosis or acidosis from occurring (see column 2, lines 35-54).

One having ordinary skill in the art at the time the invention was made would have been motivated to modify the bicarbonate and weak acid concentrations of Schambye et al. in such a way as to obtain a pCO_2 that is approximately the same as the carbon dioxide partial pressure of blood, since Zander discloses that using CO_2

partial pressures (40 mm Hg) that correspond to physiological blood plasma values would prevent alkalosis or acidosis from occurring.

9. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Veech et al. (US 4,663,166) in view of Zander (U.S. Patent No. 5,296,242).

Veech discloses peritoneal dialysis solutions as described above. The peritoneal solutions disclosed in Veech tend to maintain a normal equivalent ratio of sodium to chloride, tend to maintain normal plasma and cellular pH and tend to maintain normal cofactor ratios (see column 41, lines 9-14). Thus, upon its use the peritoneal dialysis solution of Veech would inherently correct metabolic acidosis in a dialysis patient suffering from or likely to suffer from metabolic acidosis.

Veech differs from the instant invention in that Veech does not specifically teach that the carbon dioxide partial pressure is approximately the same as the carbon dioxide partial pressure of blood.

Zander discloses sterilizable aqueous solutions that contain the claimed concentrations of the bicarbonate and weak acid, as well as the claimed carbon dioxide partial pressure (see column 2, line 35 to column 6, line 27). Zander discloses that preliminary research revealed that dialysis solutions are particularly suitable if their pH-value, bicarbonate concentration and CO_2 partial pressure correspond to the physiological blood plasma values (see column 2, lines 35-39). These physiological values are for pH value 7.40+\-0.05, for the bicarbonate concentration 24 mmole/l and for the CO_2 partial pressure 40 mm Hg (see column 2, lines 40-43). Zander discloses that using pH-values (7.40+\-0.05), bicarbonate concentrations (24 mmole/L) and CO_2

partial pressures (40 mm Hg) that correspond to physiological blood plasma values would prevent alkalosis or acidosis from occurring (see column 2, lines 35-54).

One having ordinary skill in the art at the time the invention was made would have been motivated to modify the bicarbonate and weak acid concentrations of Veech in such a way as to obtain a pCO_2 that is approximately the same as the carbon dioxide partial pressure of blood, since Zander discloses that using CO_2 partial pressures (40 mm Hg) that correspond to physiological blood plasma values would prevent alkalosis or acidosis from occurring.

Veech further differs from claim 15, in that Veech teaches utilizing lactate as the weak acid, whereas claim 15 requires that the solution does not contain lactate.

Zander teaches that in peritoneal dialysis solutions the metabolizable acids can be selected from pyruvic, lactic, oxalic, fumaric, acetic, malic, maleic, malonic and succinic acids. Thus, these acids are taught to be interchangeable.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the lactic acid of Veech with any of the metabolizable acids taught by Zander , since Zander implicitly teaches that these acids are equivalent for their use in the peritoneal dialysis art and the selection of any of these known equivalents as the weak acid in Veech would be within the level of ordinary skill in the art.

10. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Veech (US 6,020,007) in view of Zander (US 5,296,242).

Veech teaches a solution, which can be used to correct acidosis, for dialysis

and/or fluid, electrolyte or nutrient replacement (see column 7, lines 34-40). In particular the type C solutions are suitable for use in peritoneal dialysis (see column 8, lines 36-38). The components of the solution are listed in Table II in column 9. The broadest range amount of each component is given in Table II. However, Veech teaches that to be physiologically advantageous it is generally preferred to maintain levels of the components at values, which are approximately physiologic (see column 5, lines 65 to column 6, line 13). The most preferred pH of the solution is about 7.4 (see column 6, lines 44 and 45).

Veech differs from the instant invention in that Veech does not specifically teach that the carbon dioxide partial pressure is approximately the same as the carbon dioxide partial pressure of blood.

Zander discloses sterilizable aqueous solutions that contain the claimed concentrations of the bicarbonate and weak acid, as well as the claimed carbon dioxide partial pressure (see column 2, line 35 to column 6, line 27). Zander discloses that preliminary research revealed that dialysis solutions are particularly suitable if their pH-value, bicarbonate concentration and CO_2 partial pressure correspond to the physiological blood plasma values (see column 2, lines 35-39). These physiological values are for pH value 7.40+\-0.05, for the bicarbonate concentration 24 mmole/l and for the CO_2 partial pressure 40 mm Hg (see column 2, lines 40-43). Zander discloses that using pH-values (7.40+\-0.05), bicarbonate concentrations (24 mmole/L) and CO_2 partial pressures (40 mm Hg) that correspond to physiological blood plasma values would prevent alkalosis or acidosis from occurring (see column 2, lines 35-54).

One having ordinary skill in the art at the time the invention was made would have been motivated to modify the bicarbonate and weak acid concentrations of Veech in such a way as to obtain a pCO_2 that is approximately the same as the carbon dioxide partial pressure of blood, since Zander discloses that using CO_2 partial pressures (40 mm Hg) that correspond to physiological blood plasma values would prevent alkalosis or acidosis from occurring.

Response to Arguments

11. Applicant's arguments with respect to claims 1-16 have been considered but are moot in view of the new ground(s) of rejection.

However, the Examiner wishes to address some of the arguments raised in Applicants' response filed May 7, 2002.

On page 7 of Applicants' response, the Applicants' argue that the only weak acid suggested by Zander is acetate. The Examiner disagrees, in column 3, lines 61-68 and Tables I, II and III Zander discloses the use of other weak acids in addition to acetic acid for use in their peritoneal dialysis solution.

On page 7 of Applicants' response, the Applicants argue that Schambye is not directed to solving the same problem as the present invention. This argument is not persuasive because there is no requirement that the prior art must suggest that the claimed product will have the same or similar utility as that discovered by applicant in order to support a legal conclusion of obviousness. *In re Dillon*, 919 F. 2d 688, 16 USPQ 2d 1897, 1904 (Fed. Cir. 1990) (in banc), cert. denied, 111 S. Ct. 1682 (1991).

An obviousness rejection is proper under Dillon so long as the prior art suggests a reason or provides motivation to make the claimed invention, even where applicant bases the reason or motivation on one different from that discovered.

On page 9 of Applicants response, Applicants state that Schambye is not directed toward the same type of solution as required by claim 1. The Examiner disagrees. Schambye is directed to a peritoneal dialysis solution (see entire disclosure, in particular the title and abstract).

On page 10 of Applicants response, Applicants argue that the bicarbonate and weak acid ranges taught by Veech (0 to 55 mmole/L) are too broad and cover too many inoperative solutions that would result in metabolic acidosis or metabolic alkalosis if used for long term peritoneal dialysis solutions. This Examiner disagrees because in Table VIII, the preferred peritoneal dialysis solution has a bicarbonate concentration of 25 to 30 and a weak acid concentration of 2 to 12. This is quite similar to the claimed bicarbonate concentration of 20 to 30 mEq/L and the claimed weak acid concentration of 10-20 mEq/L. Thus, the peritoneal dialysis solution of Veech would not result in metabolic acidosis or metabolic alkalosis if used for long-term peritoneal dialysis solutions, and in fact Veech teaches that his solutions tend to maintain normal plasma and cellular pH (see column 41, lines 7-17). The Applicants further argue that Veech do not address the problem of metabolic acidosis in patients suffering from end stage renal failure. First, the Examiner wishes to point out that claims 11-16 are directed to a method of correcting metabolic acidosis in a dialysis patient suffering or likely to suffer from same, not a method of correcting metabolic acidosis in patients suffering from end

stage renal failure. Nonetheless, metabolic acidosis is metabolic acidosis and Veech '166 discloses in column 16, lines 11-14 that existent acidosis can be corrected by modifying the Na+:Cl- ratio. Further, Veech (US Patent No. 6,020,007) disclose at column 7, lines 33-40 that correction of acidosis can be accomplished through the use of any one or more of the various anions herein taught in a starting solution wherein the cations are selected from among hydrogen, sodium, potassium, calcium, magnesium and ammonium (see also column 3, lines 9-25).

The Applicants argue on page 10, that the composition of Veech would not be used commercially because the composition is not stable during heat sterilization. This argument is not persuasive because the Applicants have not shown that the composition of Veech cannot be used commercially because the composition is not stable during heat sterilization. Further, it appears from the teachings of Veech that his composition can be used commercially (see abstract of Veech '166 and '007).

The Applicants argue that Zander like Veech fail to teach or suggest a composition with the buffer qualities or the ability to maintain the acid-base balance in a patient according to the claimed invention. The Examiner disagrees. Zander teaches using a peritoneal dialysis solution that contains both bicarbonate and a weak acid (see column 3). Further, Zander teach that the use of the metabolizable anions of organic acids is desired for the therapy of acidosis (see column 2, line 64 to column 3, line 2). The Applicants further argue that one skilled in the art would not be motivated to combine Zander and Veech. The Examiner disagrees. Both references are directed toward peritoneal dialysis solutions, which contain both bicarbonate and a weak acid,

and both mention treating or correcting acidosis. Further, Zander provides a motivation to modify the pCO_2 of Veech, i.e., to ensure that alkalosis or acidosis is not produced (see Zander column 2, lines 35-54).

Response to Amendment

12. The declaration under 37 CFR 1.132 filed May 7, 2002 is insufficient to overcome the rejection of the claims based upon 103(a) rejection over Schambye, Zander and Veech as set forth in the last Office action because: the applicants have not made a comparison with the closest prior art of record, namely Schambye, Zander and Veech. The Dianeal solution used in the comparison contains a weak acid but does not contain bicarbonate, whereas the solutions of Schambye, Zander and Veech each contain bicarbonate as well as a weak acid. Further, the weak acid concentration used in the comparison is higher than the weak acid concentrations disclosed in the Schambye, Zander and Veech. Further, the Applicants have not shown unexpected results with respect to the claimed ranges of the individual components present in their dialysis solution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosalynd Keys whose telephone number is 703-308-4633. The examiner can normally be reached on M and F 3:00-8:00 pm and T-R 5:30-10:30 am.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 703-308-4532. The fax phone numbers

for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Rosalynd Keys
Primary Examiner
Art Unit 1621

R. Keys
July 24, 2002